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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,856	07/25/2001	David H. Mack	003848.00091	4786
28315	7590	02/05/2004	EXAMINER	
BANNER & WITCOFF LTD., ATTORNEYS FOR AFFYMETRIX 1001 G STREET , N.W. ELEVENTH FLOOR WASHINGTON, DC 20001-4597			MAHATAN, CHANNING	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 02/05/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/911,856	MACK, DAVID H.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Channing S Mahatan	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 October 2003 (RCE 16 December 2003).
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-9, 106 and 107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9, 106 and 107 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 02 May 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

### *REQUEST FOR CONTINUED EXAMINATION*

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicants' submission filed on 16 October 2003 has been entered.

Applicants' arguments, filed 16 October 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. It should be noted Applicants' arguments filed 16 October 2003 were addressed in the 'Advisory Action', mailed 20 November 2003. No new arguments and/or amendments have been filed since such time.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 1-9, 106, and 107. Claims 10-105 have been cancelled.

#### **Claims Rejected Under 35 U.S.C. § 112 1<sup>st</sup> Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

*LACK OF ENABLEMENT*

The rejection of claims 1-9, 106, and 107 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants present the following argument in the response filed 16 October 2003: "The art of statistics was well developed at the time the application was file. One skilled in the art of statistics would have been readily able to analyze a cluster map to generate a gene network of causal models using the specification as a guide and the knowledge of how to perform analysis methods." Further, Applicants reference Joreskog et al. as teaching how to generally perform the LISREL method. Applicants' arguments are unpersuasive.

While it is acknowledged Joreskog et al. teaches the general LISREL approach, it is the absence of specified parameters and assumptions for the general LISREL approach that fails to enable the claimed method. Joreskog et al. lists several parameters that are used to describe the measurement properties (validities and reliabilities) of the observed variables and the causal effects and the amount of unexplained variables (page 130, line 28 to page 132, line 21). However, absent from Joreskog et al. and the instant specification is an indication of what these parameters represent in relation to the analysis of gene cluster map and the generation of gene network causal models. Further, Joreskog et al. states "For most of our models we will consider the identification problem on a case-by-case basis" (page 134, lines 1-2) and does not disclose specified parameters and assumptions for gene network causal models to be utilized in the

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general LISREL approach. An individual skilled in the art would not have been informed as to what to do or how to adapt programs known in the art unless some type of specific procedure is set forth (i.e. specified parameters and assumptions) for gene network causal models. For example, refinement of LISREL (i.e. develop/identify parameters and assumptions) would be required to analyze the gene expression information provided by Schena et al. to generate gene network causal models. In the absence of sufficient guidance, further refinement is considered undue experimentation. Additionally, no gene network causal models are generated from the experimental work in the specification. One practicing the method as claimed would have to use his or her own inventive skill or ingenuity beyond that to be expected of one of ordinary skill in the art to adapt the known statistical techniques to this particular problem (invitation to experiment); namely generating a gene network causal model from cluster map. It should be noted Applicants arguments have been directed to LISREL, however, only claim 9 is limited to LISREL.

*FIRST ACTION FINAL FOLLOWING REQUEST FOR CONTINUED EXAMINATION*

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 C.F.R. § 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 C.F.R. § 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 C.F.R. § 1.114. See M.P.E.P. § 706.07(b). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**No Claims Are Allowed.**

*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *February 03, 2004*

Examiner Initials: *TMA*

*Marianne P. Allen*

MARIANNE P. ALLEN  
PRIMARY EXAMINER

*AS1631*